Module 4:
HIV Testing Strategies and Algorithms

Learning Objectives

At the end of this module, you will be able to:

- Discuss the process for developing a national testing algorithm
- Explain how sensitivity, specificity, positive/negative predictive value relate to development of an HIV rapid testing algorithm
- Explain the HIV rapid testing algorithm approved in your country
- Determine HIV status following a particular algorithm

Content Overview

- Testing strategies and algorithms
- Developing national testing algorithm
- Measuring performance of HIV rapid tests
- Interpreting HIV status

Strategies and Algorithms

- Strategies – Testing approach used to meet a specific need, such as:
  - Blood Safety
  - Surveillance
  - Diagnosis

- Algorithms – The combination and sequence of specific tests used in a given strategy

Strategies and Algorithms (Cont.)

- For a given strategy, multiple algorithms may be used depending on the needs of testing settings
- The number of algorithms should be limited

HIV Testing Strategies

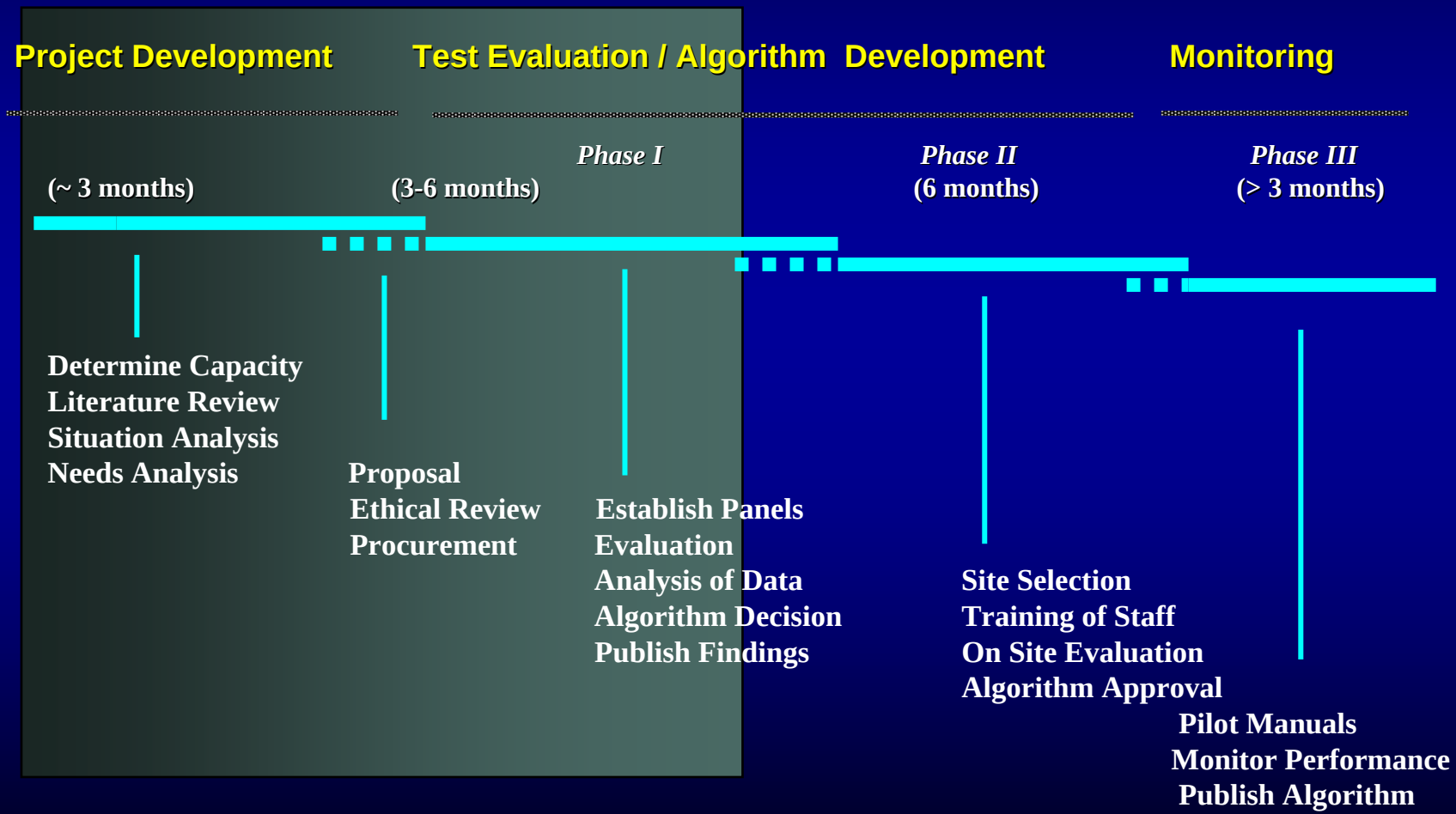
- Parallel testing
  - Samples are tested simultaneously by two different tests
- Serial testing
  - Samples tested by a first test
  - Result of first test determines whether additional testing is required

Testing Algorithms Should be Developed at National Level

Key Steps :

- Identify appropriate tests
- Develop algorithm
- Build consensus
- Develop policy
- Bring into national scale
- Review testing algorithms annually

Timeline for Developing National Testing Algorithm



Advantages of National Testing Strategies and Algorithms

Facilitates:

- Country-level standardization
- Procurement and supply management
- Training
- Quality assurance

Key Factors in Determining a Country's Algorithm

- Test performance in country
- Test availability in country
- Program needs
- Ease of use
- Type of specimen
- Cost
- Potential need to differentiate between HIV 1 & HIV 2

Evaluating Test Performance: Basic Terms

- **Sensitivity (Se)** of a test is its capacity to correctly identify people that are infected with HIV.
- **Specificity (Sp)** of a test is its capacity to correctly identify people that are not infected with HIV.
- **Positive Predictive Value (PPV)** is the probability that a person who tests reactive is indeed infected with HIV.
- **Negative Predictive Value (NPV)** is the probability that a person who tests negative is not infected with HIV.

Calculating Sensitivity, Specificity, PPV, & NPV

Test result	Actual HIV status (Gold Standard)		
	HIV **infected**	**HIV -uninfected**	**Total**
Positive	**A**	**B**	**A+B**
Negative	**C**	**D**	**C+D**
Total	**A+C**	**B+D**	

Sensitivity = A ÷ (A+C)
Specificity = D ÷ (B+D)
Positive Predictive Value = A ÷ (A+B)
Negative Predictive Value = D ÷ (C+D)

Calculating Sensitivity, Specificity, PPV, & NPV (Cont'd)

Test result	Actual HIV status (Gold Standard)		
	HIV **infected**	**HIV -uninfected**	**Total**
Positive	**A (370)**	**B (2)**	**A+B(372)**
Negative	**C (4)**	**D (624)**	**C+D(628)**
Total	**A+C (374)**	**B+D (626)**	**1000**

Sensitivity = A ÷ (A+C) = 370 ÷ 374 = 98.9%
Specificity = D ÷ (B+D) = 624 ÷ 626 = 99.7%
PPV = A ÷ (A+B) = 370 ÷ 372 = 99.5%
NPV = D ÷ (C+D) = 624 ÷ 628 = 99.4%

HIV Rapid Test Performance

- No test is 100 % sensitive
- No test is 100 % specific

Note: Performance of tests and subsequent algorithm must be determined in context of population

How Prevalence Affects PPV & NPV

$$PPV = \frac{(\text{Prevalence})\,(Se)}{(\text{Prevalence})\,(Se) + (1 - \text{Prevalence})\,(1 - Sp)}$$

$$NPV = \frac{(1-\text{Prevalence})\,(Sp)}{(1-\text{Prevalence})\,(Sp + (\text{Prevalence})\,(1 - Se)}$$

How Prevalence Affects PPV & NPV (Cont'd)

PPV for 10 % prevalence population:

$$= \frac{(10/100)\,(98.9/100)}{(10/100)\,(98.9/100) + (1- 10/100)\,(1- 99.7/100)} = 97.3\%$$

PPV for 1% prevalence population:

$$= \frac{(1/100)\,(98.9/100)}{(1/100)\,(98.9/100) + (1- 1/100)\,(1- 99.7/100)} = 76.9\%$$

Testing Algorithm Describes the Sequence of Tests to be Performed

- An HIV Positive Status should be based upon the outcome of 2 or more tests
- When two test results disagree (one is reactive, the other non-reactive), the finding is called "*discordant*." In this case, a third test must be performed.

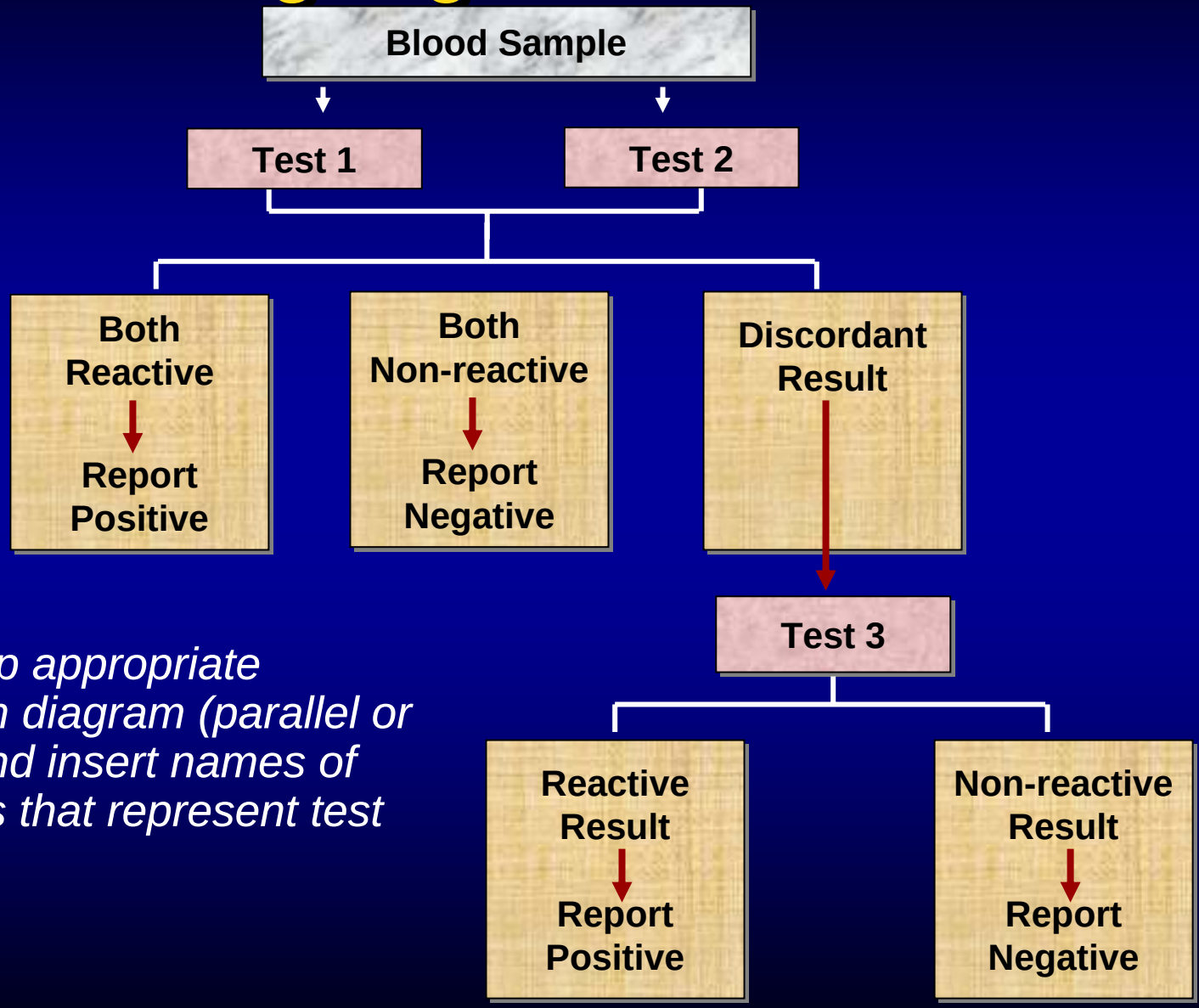
Always follow the sequence of the tests in the algorithm

- Lab workers
- Health workers
- Counselors

Ideal Algorithm

- Tests need to be :
  - Highly sensitive
  - Highly specific
- Tests should not share the same false negatives and false positives
- 3rd test (if needed)

Testing Algorithm*



** Develop appropriate algorithm diagram (parallel or serial) and insert names of HIV tests that represent test 1, 2 or 3*

Exercise: Interpreting HIV Status Using Testing Algorithm

- *Refer to Participant Manual*
- *Work alone to determine HIV status*
- *3 Minutes*

Possible HIV Test Outcomes: Parallel Algorithm

TEST 1	TEST 2	TEST 3	HIV Status
Non-reactive	Non-reactive		Negative
Reactive	Reactive		Positive
Non-reactive	Reactive	Non-reactive	Negative
Reactive	Non-reactive	Non-reactive	Negative
Non-reactive	Reactive	Reactive	Positive
Reactive	Non-reactive	Reactive	Positive

Summary

- Explain the importance of a tests' Se, Sp, PPV, NPV
- Explain the testing algorithm adopted by MoH. What rapid tests are used and in what order?